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10/665,792	09/19/2003	Scott Thomas Mazar	279.B10US1	6737
21186 7590 02/25/2009 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938			EXAMINER	
			PAULS, JOHN A	
MINNEAPOLIS, MN 55402			ART UNIT	PAPER NUMBER
			4114	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/665,792	MAZAR ET AL.			
Office Action Summary	Examiner	Art Unit			
	JOHN A. PAULS	4114			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w. - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	l. lely filed the mailing date of this communication. (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 19 Se	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1-61 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-61 is/are rejected. 7) ☐ Claim(s) 16,17,19,20,34,47-49,53-59 and 61 is 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ access	vn from consideration. v/are objected to. r election requirement. r.	Examiner.			
Applicant may not request that any objection to the orection Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Ex	drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some color None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 19 September, 2003.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	te			

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DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 19 September 2003.

2. Claims 1 - 61 are currently pending and have been examined.

Information Disclosure Statement

3. The Information Disclosure Statement filed on 19 September, 2003 has been considered. An initialed copy of the Form 1449 is enclosed herewith.

4. Claim 54 is objected to under 37 CFR 1.75 as being a duplicate of Claim 55.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 102 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 34 - 61 are rejected under 35 U.S.C. § 101 because the steps recited do not qualify as a statutory process. In order for a method to be considered a "process" under § 101, a claimed process must either: (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials). *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972). If neither of these requirements is met by the claim, the method is not a patent eligible process under 101 and is non-statutory subject matter. Although the steps are performed using a computer, the computer is a field of use limitation because the steps are human actions that do not require (i.e. are not tied to) the computer.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2 - 4 and 33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. The claims recite an "Advanced Patient Management" system, however the term is vague and indefinite because the term "Advanced" is a relative term. For purposes of this examination. Examiner will assume that the term means "Patient Management System".

- 9. Claims 30 and 32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite an "ATM-like" system; however the term is vague and indefinite. For purposes of this examination, Examiner assumes that the terms mean a publicly available terminal.
- 10. Examiner's Note: The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 12. Claim 33 is rejected under 35 U.S.C. § 102(e) as being anticipated by Leven (US PGPUB 2004/10172290 A1).

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Leven as shown discloses an implantable health monitoring device and an analysis system and method with the following limitations:

an implantable medical device adapted to sense and transmit patient health data comprising a
proximity recognition system; (see at least Leven paragraph 0048);

- an Advanced Patient Management system adapted to store patient health data and analyze
 patient health data using clinically derived algorithms in a manner consistent with a standard of
 medical care; (see at least Leven paragraph 0036 and 0041);
- a recognition module adapted to uniquely identify the medical device comprising the proximity recognition system and authorize personal access to an information portal; (see at least Leven paragraph 0036, 0041 and 0044);
- a publicly accessible information access portal adapted to convey patient health data and other information to an authorized, uniquely identified person in a multi-media presentation; (see at least Leven paragraph 0036, 0044 and 0048).

Claim Rejections - 35 USC § 103

- 13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 14. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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15. Claims 1 - 4, 11 - 20, 26 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leven (US PGPUB 2004/0172290 Al) and in further view of Kalgren et al. (US PGPUB 2002/0077562 A1)

CLAIMS 1 - 4

Leven as shown discloses a health monitoring device and an analysis system and method with the following limitations:

- a patient management system adapted to store and analyze patient health data; (see at least Leven paragraph 0036 and 0041);
- a recognition module adapted to uniquely identify a person authorized to access patient health data; (see at least Leven paragraph 0036 and 0044);
- an information access portal adapted to convey patient health data and other information to an authorized, uniquely identified person; (see at least Leven paragraph 0036 and 0044);
- the patient management system comprises an Advanced Patient Management system; (see at least Leven paragraph 0009 001 1; 0036 and 0041);
- the system is remote from the information access portal; (see at least Leven paragraph 0041).

Leven as shown discloses the limitations above. Leven does not disclose the following limitations, however, Kalgren discloses an implantable health monitoring device and an analysis system and method with the following limitations:

- an implantable medical device adapted to sense and transmit patient health data; (see at least Kalgren paragraph 0002,0003 and 0004);
- the implantable medical device comprises a component of the Advanced Patient Management system; (see at least Kalgren paragraph 0008).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven with the implantable device of Kalgren because the use of implantable devices for patient data collection allows a physician to efficiently process large amounts of data and provides a variety of clinically useful functions with which to treat patients.

CLAIMS 11 - 20

The combination of Leven/Kalgren as shown discloses the limitations above. Additionally, Leven discloses the following limitations:

• a proximity recognition system; (see at least Leven paragraph 0041);

the information access portal conveys information; (see at least Leven paragraph 0036);

• the information is conveyed in a multi-media presentation; (see at least Leven paragraph 0036);

 the presentation comprises audio, video and tactile presentations; (see at least Leven paragraph 0036).

The combination of Leven/Kalgren as shown discloses the limitations above. Leven does not disclose the following limitations, however, Kalgren does:

 a proximity reader and an implantable medical device further comprising an antennae and an integrated circuit; (see at least Kalgren paragraph 0026 and 0043);

 the information access portal conveys physiometric information; (see at least Kalgren paragraph 0003 and 0004);

• the information comprises static information; (see at least Kalgren paragraph 0008);

• the information comprises trended information; (see at least Kalgren paragraph 0010 and 0058).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven with the proximity and information access systems of Kalgren because the capability to detect an implanted device in proximity to a data collection system would allow information to be transferred without any action on the part of the patient and the data collection system allows a physician to efficiently process large amounts of data and provides a variety of clinically useful functions with which to treat patients.

CLAIMS 26 and 27

The combination of Leven/Kalgren as shown discloses the limitations above. Additionally, Leven discloses the following limitations:

 the information access portal comprises a home interface system; (see at least Leven paragraph 00038 and 0004);

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• the home interface system comprises a personal computing device; (see at least Leven paragraph 00038 and 0004).

16. Claims 5 - 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leven (US PGPUB 2004/10172290 Al) and in further view of Kalgren et al. (US PGPUB 2002/10077562 Al) and in further view of Walker et al. (US PGPUB 2002/10013173 Al).

CLAIMS 5 - 10

The combination of Leven/Kalgren as shown discloses the limitations above. Leven/Kalgren does not discloses the following limitations, however, Walker does:

- the recognition module comprises a fingerprint recognition system; (see at least Walker paragraph 0055);
- the recognition module comprises a security access card system; (see at least Walker paragraph 0083);
- the recognition module comprises a bar code scanning system; (see at least Walker paragraph 0083);
- the recognition module comprises a voice recognition system; (see at least Walker paragraph 0055);
- the recognition module comprises a facial- identification system; (see at least Walker paragraph 0083);
- the recognition module comprises a retinal scan recognition system; (see at least Walker paragraph 0055).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven/Kalgren with the recognition systems of Walker because the capability to positively identify a person would allow confidential information to be easily protected.

Examiner notes that the specification in the present application discloses that identifying a person is now possible through fingerprint, security access card, proximity, voice, facial and retinal scans. (see Background pages 2 and 3). Such disclosure constitutes applicant's own admission of prior art.

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17. Claims 21, 22,24,28 - 32, 34 - 36,43 - 51, 53 and 61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leven (US PGPUB 2004/10172290 AI) and in further view of Kalgren et al. (US PGPUB 2002/10077562 A1) and in further view of Seigel et al. (US PGPUB

2001/10051876 AI).

CLAIMS 21, 22, 24 and 28 - 30

The combination of Leven/Kalgren as shown discloses the limitations above. Leven/Kalgren does not discloses the following limitations, however, Seigel does:

- the information access portal conveys other information; (see at least Seigel paragraph 0011);
- the information is conveyed in a multi-media presentation; (see at least Seigel paragraph 0262);
- the person can configure the information; (see at least Seigel paragraph 0014);
- the home interface system comprises a portable personal computing device; (see at least Seigel paragraph 001 6);
- the information access portal comprises a kiosk; (see at least Seigel paragraph 0016);
- the information access portal comprises an ATM-like system; (see at least Seigel paragraph 0060);
- the access portal is publicly available; (see at least Seigel paragraph 0060).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven/Kalgren with the information access systems of Seigel because the capability to enter and view health information on any available computer would allow more efficient data uploads more convenient access to health data.

CLAIMS 34 - 36, 43 - 51, 53 and 61

Leven as shown discloses a health monitoring device and an analysis system and method with the following limitations:

- automatically identifying the person; (see at least Leven paragraph 0041);
- granting the automatically identified person access to an information access portal; (see at least Leven paragraph 0036 and 0041);

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implanting an identifiable medical device within the person; (see at least Leven paragraph 0008 and 0048);

- allowing the automatically identified person to enter information into the access portal; (see at least Leven paragraph 0036, 0041, 0044 and 0048);
- identifying the person using a proximity recognition system; (see at least Leven paragraph 0041);
- identifying a patient; (see at least Leven paragraph 0015, 0027 and 0041);
- identifying a clinician; (see at least Leven paragraph 0042);
- identifying a person authorized to access the access portal; (see at least Leven paragraph 0036, 0041, 0044 and 0048);
- conveying data in a multi-media format; (see at least Leven paragraph 0036);
- presenting audio, video and tactical presentations; (see at least Leven paragraph 0036);
- a proximity recognition system; (see at least Leven paragraph 0048);
- granting the automatically identified person access to a publicly accessible information access portal; (see at least Leven paragraph 0048);
- conveying information in the form of static or trended physiometric data to the automatically identified person through the information access portal in a multi-media presentation; (see at least Leven paragraph 0035, 0036, 0048).

Leven as shown discloses the limitations above. Leven does not disclose the following limitations, however, Kalgren discloses an implantable health monitoring device and an analysis system and method with the following limitations:

- conveying static physiometric data; (see at least Kalgren paragraph 0008);
- conveying trended physiometric data; (see at least Kalgren paragraph 0010 and 0058);
- conveying data comprising cardiovascular data, electro-chemical data, blood chemistry data, temperature data, wedge pressure data, oxygen saturation data, weight data, subjective wellbeing data, blood pressure data, EKG data and other physiological or psychological data; (see at least Kalgren paragraph 0008 and 0033).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven with the implantable device data of Kalgren because the use of implantable devices for patient data collection allows a physician to efficiently process large amounts of data and provides a variety of clinically useful functions with which to treat patients.

The combination of Leven/Kalgren as shown discloses the limitations above. Leven/Kalgren does not discloses the following limitations, however, Seigel does:

- conveying other information to the automatically identified person through the information access portal; (see at least Seigel paragraph 0011);
- conveying information in a multi-media format; (see at least Seigel paragraph 0262);
- conveying other information to the automatically identified person through the information access portal in a multi-media presentation; (see at least Seigel paragraph 0011 and 0262).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven/Kalgren with the information access systems of Seigel because the capability view health information in a variety of formats would allow a user to customize the presentation in accordance with their needs.

18. Claims 23 and 52 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leven (US PGPUB 2004/10172290 Al) and in further view of Kalgren et al. (US PGPUB 2002/10077562 Al) and in further view of Seigel et al. (US PGPUB 2001/10051876 Al) and in further view of Konrad (US 5,544,320 A).

CLAIMS 23 and 52

The combination of Leven/Kalgren/Seigel as shown discloses the limitations shown above. Additionally, Seigal discloses:

 the presentation comprises audio, video and tactile presentations; (see at least Seigel paragraph 0071, 0150).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven/Kalgren with the information access systems of Seigel because Art Unit: 4114

the capability view health information in a variety of formats would allow a user to customize the presentation in accordance with their needs.

The combination of Leven/Kalgren/Seigel does not specifically disclose the following limitation, however, Konrad does:

• *tactical presentations;* (see at least Konrad column 9 line 25 - 33 and column 13 Table 1 line 32 - 36).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven/Kalgren/Seigel with the tactile presentation of Konrad because the capability view health information in a tactile presentation would allow visually impaired persons access to this information.

19. Claims 25 and 60 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leven (US PGPUB 2004/10172290 Al) and in further view of Kalgren et al. (US PGPUB 2002/10077562 Al) and in further view of Seigel et al. (US PGPUB 2001/10051876 AT) and in further view of Treyz et al. (US 6,526,335 B1).

CLAIMS 25 and 60

The combination of Leven/Kalgren/Seigel as shown discloses the limitations shown above. Additionally, Seigal discloses:

 the conveyed information comprises reports of current events, weather, sports, and other information; (see at least Seigel paragraph 0153. 0083, 0098).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven/Kalgren with the other information access systems of Seigel because the capability view a variety of information in a variety of formats would allow a user to easily obtain desired information for a number of subjects.

The combination of Leven/Kalgren/Seigel as shown discloses the limitations shown above. The combination of Leven/Kalgren/Seigel does not specifically disclose the following limitation, however, Treyz does:

stock prices, economic information; (see at least Treyz column 1 line 9 - 13).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven/Kalgren/Seigel with the economic information access systems of Treyz because the capability view economic information in a variety of formats would allow a user to easily obtain the desired economic information.

20. Claims 37 - 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leven (US PGPUB 2004/10172290 Al) and in further view of Kalgren et al. (US PGPUB 2002/10077562 Al) and in further view of Seigel et al. (US PGPUB 2001/0051876 A1) and in further view of Walker et al. (US PGPUB 2002/10013173 Al).

CLAIMS 37 - 42

The combination of Leven/Kalgren/Seigel as shown discloses the limitations shown above. The combination of Leven/Kalgren/Seigel does not specifically, disclose the following limitation, however, Walker does:

- identifying the person using a fingerprint recognition system; (see at least Walker paragraph 0055);
- identifying the person using a security access card system; (see at least Walker paragraph 0083);
- identifying the person using a bar code scanning system; (see at least Walker paragraph 0083);
- identifying the person using a voice recognition system; (see at least Walker paragraph 0055);
- identifying the person using a facial-identification system; (see at least Walker paragraph 0083);
- identifying the person using a retinal scan recognition system; (see at least Walker paragraph 0055).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven/Kalgren/Seigel with the recognition systems of Walker because the capability to positively identify a person would allow confidential information to be easily protected. Examiner notes that the specification in the present application discloses that identifying a person is now possible through fingerprint, security access card, proximity, voice, facial and retinal scans. (see Background pages 2 and 3). Such disclosure constitutes applicant's own admission of prior art.

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21. Claims 54 - 59 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leven (US PGPUB 2004/10172290 Al) and in further view of Kalgren et at. (US PGPUB 2002/10077562 Al) and in further view of Seigel et al. (US PGPUB 2001/0051876 A1) and in further view of lliff et al. (US 6,234,964 B1).

CLAIMS 54 - 59

The combination of Leven/Kalgren/Seigel as shown discloses the limitations shown above. Additionally, Leven discloses the following limitation:

 comparing the physiometric data of the person to the physiometric data from a population of persons, said population physiometric data being selected by a clinician; (see at least Leven paragraph 0036 and 0041).

Examiner notes that Leven discloses "reference models" which have the same meaning as "populations" in the present application.

The combination of Leven/Kalgren/Seigel as shown discloses the limitations shown above. The combination of Leven/Kalgren/Seigel does not specifically disclose the following limitation, however, lliff does:

- comparing the physiometric data of the person to the physiometric data from a population of persons; (see at least lliff column 2 line 49 56 and column 19 line 39 41 and line 61 67);
- comparing the physiometric data of the person to the physiometric data from a population of persons; (see at least lliff column 2 line 49 56 and column 19 line 39 41 and line 61 67);
- comparing the physiometric data of the person to the physiometric data from a population of persons with a health profile similar to the person; (see at least lliff column 2 line 49 - 56 and column 19 line 39 - 41 and line 61 - 67);
- comparing the physiometric data of the person to the physiometric data from a population of persons, said population physiometric data being selected by the person; (see at least lliff column 5 line 49 67; column 11 line 17 25; and column 19 line 39 41 and line 61 67);
- comparing the physiometric data of the person to the physiometric data from a population of persons, said population physiometric data being selected by another person so authorized to

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compare and select said data; (see at least lliff column 5 line 49 - 67; column 11 line 17 - 25 and column 19 line 39 - 41 and line 61 - 67).

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the health monitoring and analysis system of Leven/Kalgren/Seigel with the analysis system of lliff because the capability to analyze health data against a population would allow a user to measure their condition against a reference and also to gain information about successful treatments.

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CONCLUSION

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Any inquiry of a general nature or relating to the status of this application or concerning this

communication or earlier communications from the Examiner should be directed to John A. Pauls whose

telephone number is 571-270-5557. The Examiner can normally be reached on Monday-Friday, 9:30am-

5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor,

JAMES A. REAGAN can be reached at 571.272.6710.

Information regarding the status of an application may be obtained from the Patent Application

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Date: 13 February, 2009

JOHN A. PAULS/

Examiner, Art Unit 4114

/James A. Reagan/

Supervisory Patent Examiner, Art Unit 4114